

## **REMARKS/ARGUMENTS**

The election/restriction requirement dated October 10, 2006 has been considered. Claims 1-95 are pending in the application. Claims 41-77 and 95 have been canceled without prejudice or disclaimer, as being directed to non-elected inventions. Applicant hereby provisionally elects claims 1-40 and 78-80 of Invention I. Applicant traverses the restrictions between Inventions I, III and IV.

While not acquiescing to the Examiner's distinction between claims 1-40 and 78-80, identified by the Examiner as Invention I, claims 41-77, identified by the Examiner as Invention II, claims 81-89, identified by the Examiner as Invention III, claims 90-94, identified by the Examiner as Invention IV, and claim 95, identified by the Examiner as Invention V, the Applicant will use this convention for convenience in addressing the restriction herein.

Restriction based on combination/subcombination classification requires that the subcombination be shown to have utility either by itself or in another materially different combination. (MPEP § 806.05(c)). The Examiner states that "[t]he subcombination [of Inventions III and IV] has separate utility such as detection systems without electrodes as claimed." (Office Action, Page 2).

The Applicant respectfully submits that the basis for requiring restriction is in error. The Applicant respectfully clarifies that detection systems of the type contemplated in the disclosure can not function as detection systems that detect cardiac electrical activity without electrodes, such as those recited in the pending claims.

Moreover, the identified combination and subcombinations each implicate electrodes that include some combination of intrathoracic and subcutaneous non-intrathoracic, as claimed. Each independent claim of Inventions I, III and IV recites at least two configurations, and in each configuration electrodes of these two types are implicated, such that no claim includes a detection system without recitation of electrodes of these two types.

For example, independent claim 1 of Invention I recites "the system operable in a first configuration using the one or more subcutaneous electrodes in the absence of the at least one lead and operable in a second configuration using at least the one or more lead electrodes," wherein the one or more subcutaneous electrodes is/are configured for subcutaneous, non-

intrathoracic placement and the one or more lead electrodes is/are recited as configured for intrathoracic placement.

Independent claim 32 of Invention I recites “the system operable in a first configuration using the one or more subcutaneous electrodes in the absence of the at least one lead and operable in a second configuration using at least the one or more lead electrodes,” wherein the one or more subcutaneous electrodes is/are configured for subcutaneous, non-intrathoracic placement and the one or more lead electrodes is/are recited as configured for intrathoracic placement.

Moreover, independent claim 81 of Invention III recites “the controller configuring the system to operate in a first configuration by enabling only the first electrode connection arrangement and to operate in a second configuration by enabling at least the second electrode connection arrangement,” wherein the first electrode connection arrangement is recited as being configured for coupling with one or more subcutaneous, non-intrathoracic electrodes and the second electrode connection arrangement is recited as being configured for coupling with one or more intrathoracic electrodes.

Also, independent claim 90 of Invention IV recites “the system operable in a first configuration using only the subcutaneous non-intrathoracic electrode arrangement, in a second configuration using only the intrathoracic electrode arrangement, and in a third configuration using the non-intrathoracic and intrathoracic electrode arrangements.”

Contrary to the Examiner’s assertion in support of the restriction between Invention I and Inventions III and IV, each configuration recited in each independent claim of Inventions I, III, and IV implicates electrodes that are necessary for the recited systems to operate as detection systems, the electrodes including some combination of intrathoracic and subcutaneous, non-intrathoracic electrodes. As such, the Applicant respectfully submits that the Examiner’s proposed separate utility of the subcombination is in error and restriction improper.

In support of the restriction between Inventions III and IV, The Examiner states that “[t]he subcombination IV has separate utility such as an implantable stimulator with specific electrode interface structure.” (Office Action, Page 2).

The Applicant respectfully submits that the Examiner's identification of a "separate utility" is in error, and that the Examiner has therefore not met the burden of establishing the existence of a separate utility for the subcombination as is required to support the Examiner restriction requirement.

Both Inventions III and IV recite structure that facilitates electrode coupling. For example, independent claim 81 of Invention III recites "the switching matrix comprising first and second electrode connection arrangements, the first electrode connection arrangement configured for coupling with one or more subcutaneous, non-intrathoracic electrodes and the second electrode connection arrangement configured for coupling with one or more intrathoracic electrodes." Independent claim 90 of Invention IV recites "the interface configured to receive at least one intrathoracic electrode arrangement and at least one subcutaneous non-intrathoracic electrode arrangement." Inventions III and IV recite electrode connectivity structures that have a common utility—coupling various electrodes. As such, the purported *separate* utility of Invention IV identified by the Examiner is clearly in error.

In order to establish reasons for insisting upon restriction, the Examiner must explain why there would be a serious burden on the Examiner if restriction is not required. (See, MPEP § 808.01(a) which references MPEP § 808.02). To comply with this requirement, the Examiner must show by appropriate explanation one of the following (1) separate classification; (2) separate status in the art when they are classifiable together, or (3) a different field of search. (MPEP § 808.02).

The Examiner states that the inventions "have acquired a separate status in the art due to their recognized divergent subject matter." (Office Action, Page 5). Section 808.02 of the MPEP, under the heading "Establishing Burden," states that "[s]eparate status in the art may be shown by citing patents which are evidence of such separate status."

The Applicant respectfully submits that the Examiner has failed to meet his burden and only provides a conclusory statement asserting that the inventions have separate status in the art. The Examiner does not explain or provide support in his conclusion that the subject matter of each respective invention has been recognized as having acquired separate status in the art. Instead, the fact that the inventions are grouped together in class 607, subclass 9,

undermines the Examiner's statement that the inventions have acquired a separate status in the art.


The Examiner further states that a serious burden exists "due to the vast number of claims in the case." (Office Action, Page 5). The Applicant respectfully submits that the burden has been substantially reduced because claims 41-77 and 95 of Inventions II and IV have been canceled, and all pending claims can be subject to search in the same search class and subclass. The fact that the inventions are grouped together in subclass 9 of class 607 supports the Applicant's position that examination of the inventions together does not meet the serious burden requirement for proper restriction. Accordingly, examination of the remaining claims together would not present a serious burden.

For at least these reasons, the Applicant submits that the Examiner has not presented the evidence required to satisfy the burden of maintaining the restriction requirement. Without such evidence, the restriction requirement is improper. Accordingly, the Applicant requests that the restriction requirement to Inventions I, III and IV be withdrawn.

In view of the above, the Applicant respectfully requests reconsideration and withdrawal of the requirement for restriction. If the Examiner would find it helpful to discuss this issue by telephone, the undersigned attorney of record invites the Examiner to contact the attorney of record.

Respectfully submitted,

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